

Application No.: 10/716,739

Applicant: PANDIAN et al.

Filed: November 18, 2003

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Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1-22. (Cancelled)

23. (Currently amended) A method for detecting a trophoblastic disease in a subject comprising the steps of:

contacting a biological sample obtained from a subject with antibodies that specifically bind hyperglycosylated human chorionic gonadotropin and human chorionic gonadotropin, in one assay;

determining an amount of hyperglycosylated human chorionic gonadotropin present in the biological sample;

determining an amount of human chorionic gonadotropin present in the biological sample;

confirming that the subject is not pregnant;

comparing the determined amount of hyperglycosylated human chorionic gonadotropin present in the sample to a 50th percentile of amounts of hyperglycosylated human chorionic gonadotropin present in samples obtained from subjects who do not have a trophoblastic disease; and

comparing the determined amount of human chorionic gonadotropin present in the sample to a 50th percentile of amounts of human chorionic gonadotropin present in samples obtained from subjects who do not have a trophoblastic disease,

wherein an amount of hyperglycosylated human chorionic gonadotropin or an amount of human chorionic gonadotropin present in the sample which is greater than the 50th percentile of the amounts of hyperglycosylated human chorionic gonadotropin or human chorionic gonadotropin present in the standards, respectively, indicates the presence of a trophoblastic disease.

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- a) ~~contacting a biological sample from the subject with antibodies that specifically bind hTA and hCG, in one assay;~~
- b) ~~confirming that the subject is not pregnant; and~~
- c) ~~comparing the amounts of hTA and hCG in the sample to standard hTA and hCG amounts obtained from a population of normal subjects, wherein a higher amount of hTA and hCG in the sample as compared to the standards indicates the presence of a trophoblastic disease.~~

24. (Original) The method of claim 23, wherein the trophoblastic disease is a choriocarcinoma.

25. (Original) The method of claim 23, wherein the trophoblastic disease is a hydatidiform mole.

26-41. (Cancelled)

42. (New) The method of claim 23, wherein the sample is selected from the group consisting of liquid samples, and tissue samples.

43. (New) The method of claim 23, wherein the determining step comprises detecting a signal produced by a label.

44. (New) The method of claim 43, wherein the signal is a chemiluminescent signal.

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45. (New) A method for detecting a trophoblastic disease in a subject comprising the steps of:

contacting a biological sample obtained from a subject with antibodies that specifically bind hyperglycosylated human chorionic gonadotropin in an assay;

confirming that the subject is not pregnant; and

determining an amount of hyperglycosylated human chorionic gonadotropin present in the biological sample, wherein an amount of hyperglycosylated human chorionic gonadotropin greater than about 400,000 ng/mL indicates the presence of a trophoblastic disease.

46. (New) The method of claim 45, wherein the trophoblastic disease is a choriocarcinoma.

47. (New) The method of claim 45, wherein the trophoblastic disease is a hydatidiform mole.

48. (New) The method of claim 45, wherein the sample is selected from the group consisting of liquid samples, and tissue samples.

49. (New) The method of claim 45, wherein the determining step comprises detecting a signal produced by a label.

50. (New) The method of claim 49, wherein the signal is a chemiluminescent signal.